

In re application of:

SETTE et al.

Appl. No.: 09/894,018

Filed: June 27, 2001

For: Method and System for

> **Optimizing Minigenes and Peptides Encoded Thereby**

Confirmation No.: 7107

Art Unit:

1631

Examiner:

Ardin H. Marschel

Atty. Docket: 2060.0320003/EKS/PAC

## First Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450 Sir:

Mail Stop Amendment

Listed on accompanying Forms PTO/SB/08a and PTO/SB/08b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of all U.S. Patents and U.S. Patent Application Publications, cited on Form PTO/SB/08a as documents US1-US15, are not provided in accordance with 37 C.F.R. § 1.98(a)(2).

Copies of documents NPL69-NPL72 cited on Form PTO/SB/08b are not provided in accordance with the U.S. Patent and Trademark Office OG notice of October 19, 2004, which states: "the requirement in 37 C.F.R. § 1.98(a)(2)(iii) for a legible copy of the specification, including the claims, and drawings of each cited pending U.S. patent application (or portion of the application which caused it to be listed) is sua sponte waived where the cited pending application is stored in the USPTO's IFW system."

The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The

Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Forms PTO/SB/08a and PTO/SB/08b based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Forms PTO/SB/08a and PTO/SB/08b, and indicate in the official file wrapper of this patent application that the documents have been considered. The U.S. Patent and Trademark Office is

hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Eric K. Steffe

Attorney for Applicants Registration No. 36,688

Date: 9/9/3) 1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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PTO/SB/08A (08-03)

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/894,018	
Filing Date	June 27, 2001	
First Named Inventor	SETTE	
Art Unit	1631	
Examiner Name	Ardin H. Marschel	
Attorney Docket Number	2060.0320003/EKS/PAC	

			U.S. PATENT D			
Examiner Initials*	Cite No.1				Relevant Pa Columns, L	
Initials					Columnis, E	
	USI	5,200,320	04/06/1993	Sette et al.		·.
	US2	5,503,829	04/02/1996	Ladant et al.		_
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			FOREIGN PATENT			
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Pages, Columns, Lines	T <sup>6</sup>
Initials	FP1	EP 0 044 710 A1	01/27/1982	Scripps Clinic & Research Foundation	001411111111111111111111111111111111111	
	FP2	EP 0 226 513 A1	06/24/1987	Institut Pasteur		Abs
	FP3	WO 92/02543 A1	02/20/1992	Cytel Corp. et al.	,	
	FP4	WO 92/12996 A2	08/06/1992	Immune Response Corp.		
	FP5	WO 92/21033 A1	11/26/1992	Max-Planck-Gesellschaft		Abs
	FP6	WO 93/03764 A1	03/04/1993	Cytel Corp.		
	FP7	WO 94/03205 A1	02/17/1994	Cytel Corp.		
	FP8	WO 94/11738 A1	05/26/1994	Max-Planck-Gesellschaft		Abs
	FP9	WO 94/20127 A1	09/15/1994	Cytel Corp.		
	FP10	WO 95/04817 A1	02/16/1995	Cytel Corp.		
	FP11	WO 95/22317 A1	08/24/1995	Cytel Corp.		

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English language Translation is attached.

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				Application Number	09/894,018		
F	IRST	<b>SUPP</b>	LEMENTAL	Filing Date	June 27, 2001		
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~		DI 1 2		Examiner Name	Ardin H. Marschel		
Sheet	7	of	2	Attorney Docket Number	2060.0320003/EKS/PAC		

	U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2 (If Known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Pages, Columns, Lines			
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			FOREIGN PATENT D	OCUMENTS		
Examiner Initials*	Cite No.	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Pages, Columns, Lines	T <sup>6</sup>
	FP12	WO 96/03140 A1	02/08/1996	Cytel Corp.		
	FP13	WO 97/33602 A1	09/18/1997	Cytel Corp.		
	FP14	WO 97/34621 A1	09/25/1997	Cytel Corp.		
	FP15	WO 98/32456 A1	07/30/1998	Epimmune Inc.		
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	FP19	WO 99/65522 A1	12/23/1999	Epimmune Inc.		
	FP20	WO 02/20616	03/14/2002	Epimmune Inc.		
	FP21	WO 02/061435 A2	08/08/2002	Epimmune Inc.		

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## INFORMATION DISCLOSURE **STATI**

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E	MEN	T BY	APPLICANT	Art Unit	1631	
				Examiner Name	Ardin H. Marschel	
	1	of	8	Attorney Docket Number	2060.0320003	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author, title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher	T <sup>2</sup>
•	NPL1	Aichele, P., et al., "Antiviral cytotoxic T cell response induced by in vivo priming with a free synthetic peptide," J. Exp. Med. 171:1815-1820, Rockefeller University Press (1990)	
	NPL2	Alexander, J., et al., "Derivation of HLA-A11/Kb Transgenic Mice. Functional CTL Repertoire and Recognition of Human A11-Restricted CTL Epitopes," J. Immunol. 159:4753-4761, The American Association of Immunologists (November 1997)	
	NPL3	Bertoni, R., et al., "Human Class I Supertypes and CTL Repertoires Extend to Chimpanzees," J. Immunol. 161:4447-4455, American Association of Immunologists (October 1998)	
	NPL4	Bjorkman, P.J., et al., "Structure of the human class I histocompatibility antigen, HLA-A2," <i>Nature 329</i> :506-512, Macmillan Publishers, Ltd. (1987)	
	NPL5	Bjorkman, P.J., et al., "The foreign antigen binding site and T cell recognition regions of class I histocompatibility antigens," <i>Nature 329</i> :512-518, Macmillan Publishers, Ltd. (1987)	
:	NPL6	Buus, S., et al., "Autologous Peptides Constitutively Occupy the Antigen Binding Site on Ia," Science 242:1045-1047, American Association for the Advancement of Science (1988)	
	NPL7	Carreno, B.M., et al., "HLA-B37 and HLA-A2.1 molecules bind largely nonoverlapping sets of peptides," <i>Proc. Natl. Acad. Sci. USA</i> 87:3420-3424, National Academy Press (1990)	
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	NPL9	De Bruijn, M.L.H., et al., "Peptide loading of empty major histocompatibility complex molecules on RMA-S cells allows the induction of primary cytotoxic T lymphocyte responses," Eur. J. Immunol. 21:2963-2970, VCH Verlagsgesellschaft mbH (1991)	

Examiner		Date	
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO					Con	nplete if Known
					Application Number	09/894,018
FIF	RST SU	<b>IPPL</b>	EMENTAL		Filing Date	June 27, 2001
INFO	INFORMATION DISCLOSURE			RE	First Named Inventor	SETTE
STAT	<b>EMEN</b>	T BY	APPLICA	NT	Art Unit	1631
					Examiner Name	Ardin H. Marschel
Sheet	2	of	8		Attorney Docket Number	2060.0320003

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Examiner Initials*	Cite No.1	Include name of the author, title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher	T <sup>2</sup>
	NPL10	Deres, K., et al., "In vivo priming of virus-specific cytotoxic T lymphocytes with synthetic lipopeptide vaccine," Nature 342:561-564, Macmillan Publishers, Ltd. (1989)	
	NPL11	DiBrino, M., et al., "HLA-A1 and HLA-A3 T Cell Epitopes Derived from Influenza Virus Proteins Predicted from Peptide Binding Motifs," J. Immunol. 151:5930-5935, The Association of Immunologists (December 1993)	
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	NPL13	Ding, YH., et al., "Two Human T Cell Receptors Bind in a Similar Diagonal Mode to the HLA-A2/Tax Peptide Complex Using Different TCR Amino Acids," <i>Immunity</i> 8:403-11, Cell Press (April 1998)	
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	NPL16	Falk, K., et al., "Allele-specific motifs revealed by sequencing of self-peptides eluted from MHC molecules," <i>Nature 351</i> :290-296, Macmillan Publishers, Ltd. (1991)	
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				Application Number	09/894,018
FIR	RST SU	PPL	<b>EMENTAL</b>	Filing Date	June 27, 2001
INFORMATION DISCLOSURE				First Named Inventor	SETTE
STAT	EMEN	ТВ	APPLICANT	Art Unit	1631
				Examiner Name	Ardin H. Marschel
Sheet	3	of	8	Attorney Docket Number	2060.0320003

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of the author, title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher	T <sup>2</sup>
	NPL20	Falk, K., et al., "Peptide motifs of HLA-A1, -A11, -A31, and -A33 molecules," Immunogenetics 40:238-241, Springer-Verlag (July 1994)	
	NPL21	Foon, K.A., "Biological Response Modifiers: The New Immunotherapy," Cancer Res. 49:1621-1639, American Association for Cancer Research (1989)	
	NPL22	Geysen, H.M., et al., "Cognitive Features of Continuous Antigenic Determinants," J. Mol. Recognit. 1:32-41, Heyden & Sons, Ltd. (1988)	
	NPL23	Guo, HC., et al., "Different length peptides bind to HLA-Aw68 similarly at their ends but bulge out in the middle," <i>Nature 360</i> :364-366, Macmillan Publishers, Ltd. (November 1992)	
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	NPL26	Jameson, S.C., and Bevan, M.J., "Dissection of major histocompatibility complex (MHC) and T cell receptor contact residues in a K <sup>b</sup> -restricted ovalbumin peptide and an assessment of the predictive power of MHC-binding motifs," <i>Eur. J. Immunol.</i> 22:2663-2667, VCH Verlagsgesellschaft mbH (October 1992)	
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Sheet	4	of	8	Attorney Docket Number	2060.0320003

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author, title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher	T <sup>2</sup>
-	NPL29	Kast, W.M., et al., "Protection against lethal Sendai virus infection by in vivo priming of virus-specific cytotoxic T lymphocytes with a free synthetic peptide," Proc. Natl. Acad. Sci. USA 88:2283-2287, National Academy Press (1991)	
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	NPL33	Maryanski, J.L., et al., "Synthetic peptides as antigens and competitors in recognition by H-2-restricted cytolytic T cells specific for HLA," J. Exp. Med. 167:1391-1405, Rockefeller University Press (1988)	
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	NPL37	Ochoa-Garay, J., et al., "The ability of peptides to induce cytotoxic T cells in vitro does not strongly correlate with their affinity for the H-2L <sup>d</sup> molecule: implications for vaccine design and immunotherapy," Mol. Immunol. 34:273-281, Elsevier Science, Ltd. (February 1997)	

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute fo	or form 144	9/PTO			Con	nplete if Known
					Application Number	09/894,018
FIF	RST SU	PPL	<b>EMENTAL</b>		Filing Date	June 27, 2001
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				RE	First Named Inventor	SETTE
				T	Art Unit	1631
			`-	Examiner Name	Ardin H. Marschel	
Sheet	5	of	8		Attorney Docket Number	2060.0320003

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author, title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher	T <sup>2</sup>
	NPL38	Pamer, E.G., et al., "Precise prediction of a dominant class I MHC-restricted epitome of Listeria monocytogenes," Nature 353:852-855, Macmillan Publishers, Ltd. (1991)	
	NPL39	Parham, P., et al., "The Origins of HLA-A,B,C Polymorphism," Immunol. Rev. 143:141-180, Munksgaard (February 1995)	
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	NPL44	Romero, P., et al., "H-2K <sup>d</sup> -restricted Antigenic Peptides Share a Simple Binding Motif," J. Exp. Med. 174:603-612, Rockefeller University Press (1991)	
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	NPL46	Rötzschke, O., et al., "Isolation and analysis of naturally processed viral peptides as recognized by cytotoxic T cells," <i>Nature 348</i> :252-254, Macmillan Publishers, Ltd. (1990)	
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Signature	-	Considered	

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					Application Number	09/894,018
FIR	RST SU	PPL	EMEN	TAL	Filing Date	June 27, 2001
INFORMATION DISCLOSURE					First Named Inventor	SETTE
STAT	EMEN <sup>i</sup>	ТВ	APPL	ICANT	Art Unit	1631
					Examiner Name	Ardin H. Marschel
Sheet	6	of	8		Attorney Docket Number	2060.0320003

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author, title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher	T <sup>2</sup>
	NPL48	Rötzschke, O., and Falk, K., "Naturally-occurring peptide antigens derived from the MHC class-I-restricted processing pathway," <i>Immunol. Today 12</i> :447-455, Elsevier Science Publishers, Ltd. (1991)	
	NPL49	Rötzschke, O., et al., "Peptide motifs of closely related HLA class I molecules encompass substantial differences," Eur. J. Immunol. 22:2453-2456, VCH Verlagsgesellschaft mbH (September 1992)	
	NPL50	Rötzschke, O., and Falk, K., "Origin, structure and motifs of naturally processed MHC class II ligands," <i>Curr. Opin. Immunol.</i> 6:45-51, Current Biology, Ltd. (February 1994)	
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	NPL54	Sette, A., et al., "Prediction of major histocompatibility complex binding regions of protein antigens by sequence pattern analysis," <i>Proc. Natl. Acad. Sci. USA 86</i> :3296-3300, National Academy Press (1989)	
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	NPL56	Sette, A., et al., "The Relationship Between Class I Binding Affinity and Immunogenicity of Potential Cytotoxic T Cell Epitopes," J. Immunol. 153:5586-5592, The American Association of Immunologists (December 1994)	
	NPL57	Sherman, L.A., et al., "Extracellular Processing of Peptide Antigens That Bind Class I Major Histocompatibility Molecules," J. Exp. Med. 175:1221-1226, The Rockefeller University Press (May 1992)	

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Substitute fo	or form 144	9/PTO		Con	nplete if Known
				Application Number	09/894,018
FIRST SUPPLEMENTAL			<b>EMENTAL</b>	Filing Date	June 27, 2001
INFO	INFORMATION DISCLOSURE			First Named Inventor	SETTE
STAT	EMEN	ТВ	APPLICANT	Art Unit	1631
			Examiner Name	Ardin H. Marschel	
Sheet	7	of	8	Attorney Docket Number	2060.0320003

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author, title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher	T <sup>2</sup>
	NPL58	Shimojo, N., et al., "Specificity of peptide binding by the HLA-A2.1 molecule," J. Immunol. 143:2939-2947, The American Association of Immunologists (1989)	
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	NPL61	Whitton, J.L., et al., "Molecular Analyses of a Five-Amino-Acid Cytotoxic T-Lymphocyte (CTL) Epitope: an Immunodominant Region Which Induces Nonreciprocal CTL Cross-Reactivity," J. Virol. 63:4303-4310, American Society for Microbiology (1989)	
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:	NPL63	York, I.A., and Rock, K.L., "Antigen processing and presentation by the class I major histocompatibility complex," <i>Annu. Rev. Immunol. 14</i> :369-396, Annual Reviews, Inc. (April 1996)	
	NPL64	Zhang, Q-J., et al., "An HLA-A11-specific motif in nonamer peptides derived from viral and cellular proteins," <i>Proc. Natl. Acad. Sci. USA 90</i> :2217-2221, National Academy Press (March 1993)	
_	NPL65	Parker, K.C., et al., "Scheme for Ranking Potential HLA-A2 Binding Peptides Based on Independent Binding of Individual Peptide Side-Chains," J. Immunol. 152:163-175, The American Association of Immunologists (January 1994)	
:	NPL66	Dialog File 351, Accession No. 7180926, Derwent WPI English language abstract for EP 0 226 513 (Document AM1)	
	NPL67	Dialog File 351, Accession No. 9263567, Derwent WPI English language abstract for WO 92/21033 (Document AP1)	

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Attorney Docket Number

<u> </u>		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author, title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher	T <sup>2</sup>
	NPL68	Dialog File 351, Accession No. 9888606, Derwent WPI English language abstract for WO 94/11738 (Document AN2)	
	NPL69	U.S. Patent Application No. 08/349,177, Grey et al., filed December 2, 1994 (NOT PUBLISHED)	
	NPL70	U.S. Patent Application No. 09/017,735, Grey et al., filed February 3, 1998 (NOT PUBLISHED)	
	NPL71	U.S. Patent Application No. 09/189,702, Sette et al., filed December 10, 1998 (NOT PUBLISHED)	
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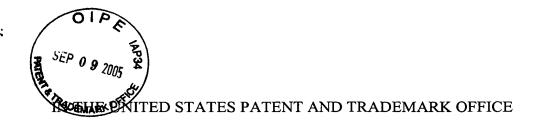
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In re application of:

SETTE et al.

Appl. No.: 09/894,018

Filed: June 27, 2001

For:

Method and System for

**Optimizing Minigenes and Peptides Encoded Thereby**  Confirmation No.: 7107

Art Unit:

1631

Examiner:

Ardin H. Marschel

Atty. Docket: 2060.0320003/EKS/PAC

## **Second Supplemental Information Disclosure Statement**

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450 Sir:

Mail Stop Amendment

Listed on accompanying Forms PTO/SB/08a and PTO/SB/08b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of all U.S. Patents and U.S. Patent Application Publications, cited on Form PTO/SB/08a as documents AA100-AJ100, AA101-AJ101 and AA102-AC102, are not provided in accordance with 37 C.F.R. § 1.98(a)(2).

A Copy of document NPL149 cited on Form PTO/SB/08b is not provided in accordance with the U.S. Patent and Trademark Office OG notice of October 19, 2004, which states: "the requirement in 37 C.F.R. § 1.98(a)(2)(iii) for a legible copy of the specification, including the claims, and drawings of each cited pending U.S. patent application (or portion of the application which caused it to be listed) is sua sponte waived where the cited pending application is stored in the USPTO's IFW system."

The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Forms PTO/SB/08a and PTO/SB/08b based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Forms PTO/SB/08a and PTO/SB/08b, and indicate in the official file wrapper of this patent application that the documents have been considered. The U.S. Patent and Trademark Office is

hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Eric K. Steffe

Attorney for Applicants Registration No. 36,688

1100 New York Avenue, N.W. Washington, D.C. 20005-3934

(202) 371-2600

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PTO/SB/08a (08-03)

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE cition Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Inder the Paperwork P Substitute for form 1449A/P Complete If Known Application Number 09/894,018 SECOND SUPPLIEMENTAL Filing Date June 27, 2001 INFORMATION DISCLOSURE First Named Inventor SETTE STATEMENT BY APPLICANT Art Unit Examiner Name Ardin H. Marschel (Use as many sheets as necessary) Attorney Docket Number 2060.0320003/EKS/PAC 2 Sheet of

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Exami ner	Cite	Document Number	Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevant Passages
Initials*	No. <sup>1</sup>	Number-Kind Code <sup>2 (If Known)</sup>	Number-Kind Code <sup>2 (If Known)</sup> MM-DD-YYYY		or Relevant Figures Appear
	AA100	4,235,877	11/25/1980	Fullerton	
	AB100	4,487,715	12/11/1984	Nitecki et al.	
	AC100	4,599,230	07/08/1986	Milich et al.	
	AD100	4,837,028	06/06/1989	Allen	
-	AE100	5,013,548	05/07/1991	Haynes et al.	
	AF100	5,128,319	07/07/1992	Arlinghaus	
	AG100	5,783,567	07/21/1998	Hedley et al.	
<del></del>	AH100	6,037,135	03/14/2000	Kubo et al.	
	Al100	6,413,935	07/02/2002	Sette et al.	
	AJ100	6,419,931	07/16/2002	Vitiello et al.	
	AA101	6,602,510	08/05/2003	Fikes et al.	
	AB101	2002/0160960	10/31/2002	Sette et al.	
	AC101	2002/0168374	11/14/2002	Kubo et al.	
	AD101	2003/0143672	07/31/2003	Tangri et al.	
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<del></del>	AF101	2003/0216343	11/20/2003	Fikes et al.	
	AG101	2004/0096445	05/20/2004	Sidney et al.	

			FOREIGN PATENT DOC	UMENTS		
Examin er Initials*	Cite No.1	Foreign Patent Document Country Code <sup>4</sup> Kind Code <sup>5</sup> (in known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵
	AL100	EP 0 378 881	06/09/1993	Eniricerche S.p.A.		
	AM100	EP 0 429 816	06/05/1991	F. Hoffmann-La Roche AG		
	AN100	EP 0 433 242	06/19/1991	Fondazione Andrea Cesalpino		
	AO100	WO 93/03764	03/04/1993	Cytel Corporation		
	AP100	WO 94/20127	09/15/1994	Cytel Corporation		
	AQ100	WO 95/07707	03/23/1995	Cytel Corporation		

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Complete If Known Application Number 09/894,018 June 27, 2001 First Named Inventor SETTE 1631 Examiner Nāmē Ardin H. Marschel Attorney Docket Number 2060.0320003/EKS/PAC

Examiner	au 1	Document Number	Publication Date	Name of Patentee	Pages, Columns, Lines, Where
Initials*	Cite No. <sup>1</sup>	Number-Kind Code <sup>2 (If</sup>	MM-DD-YYYY	or Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
	AH101	2004/0157273	08/12/2004	Sidney et al.	
	Al101	2005/0049197	03/03/2005	Sette et al.	
	AJ101	4,599,231	07/08/1986	Milich et al.	
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<u> </u>	AB102	2002/0119127	08/29/2002	Sette et al.	
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			FOREIGN PATENT DOC	UMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>4</sup> Kind Code <sup>5</sup> (in known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т <sup>6</sup>
	AM101	WO 96/22067	07/25/1996	United Biomedical		
	AN101	WO 97/41440	11/06/1997	Rijksuniversiteit te Leiden and Seed Capita Investments	al	
	AO101	WO 97/34617	09/25/1997	Cytel Corporation		
	AP101	WO 01/00225	01/04/2001	Epimmune Inc.		
Examiner Sig	nature			Date Consider	ed	

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Complete If Known Substitute for form 1449B/PTO SECOND SUPPLEMENTAL Application Number June 27, 2001 INFORMATION DISCLOSURE Filing Date SETTE STATEMENT BY APPLICANT First Named Inventor 1631 Art Unit (Use as many sheets as necessary) Ardin H. Marschel Examiner Name 2060.0320003/EKS/PAC 9 Sheet of Attorney Docket Number

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published	T
	NPL81	Alexander, J., et al., "Development of High Potency Universal DR-Restricted Helper Epitopes by Modification of High Affinity DR-Blocking Peptides," <i>Immunity</i> 1:751-761, Cell Press (1994)	
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				Com	plete If Known
Substitute for				Application Number	09/894,018
SE	CONE	SUPP	LEMENTAL	Application Number	June 27, 2001
INFO	TRMA	TION D	ISCLOSURE	Filing Date	
			APPLICANT	First Named Inventor	SETTE
				Art Unit	1631
	(Ose as	many sheets a	is necessary)	Examiner Name	Ardin H. Marschel
Sheet	2	of	9	Attorney Docket Number	2060.0320003/EKS/PAC

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
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			ISCLOSURE	Filing Date	June 27, 2001
			APPLICANT	First Named Inventor	SETTE
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Sheet	3	of	9	Attorney Docket Number	2060.0320003/EKS/PAC

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
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Sheet	4	of	9	Attorney Docket Number	2060.0320003/EKS/PAC

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL107	Kumar, A., et al., "Universal T Helper Cell Determinants Enhance Immunogenicity of a Plasmodium falciparum Merozoite Surface Antigen Peptide," J. Immunol. 148:1499-1505, American Association of Immunologists (1992)	
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		NON PATENT LITERATURE DOCUMENTS	
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NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>	
_	NPL133	Sprent, J., and Schaefer, M., "Properties of Purified T Cell Subsets. I. In Vitro Responses to Class I vs. Class II H-2 Alloantigens," <i>J. Exp. Med. 162</i> :2068-2088, Rockefeller University Press (1985)		
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	NPL142	Wentworth, P.A., et al., "In Vitro Induction of Primary, Antigen-Specific CTL from Human Peripheral Blood Mononuclear Cells Stimulated with Synthetic Peptides," Mol. Immunol. 32:603-612, Elsevier Science Ltd. (1995)		

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1	INFORMATION DISCLOSURE				SETTE		
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(Use as many sheets as necessary)			s riecessary)		Ardin H. Marschel		
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	NPL143	Widmann, C., et al., "T helper epitopes enhance the cytotoxic response of mice immunized with MHC class I-restricted malaria peptides," J. Immunol. Meth. 155:95-99, Elsevier Science Publishers B.V. (1992)		
	NPL144	Wiesmüller, K-H., et al., "Lipopeptide-Helper-T-Cell Epitope-CTL Epitope Conjugate Induces Antibodies Against the CTL Epitope," Innovation Perspective Solid Phase Synthesis Collect. Papers, Int. Symp. 2nd, pp. 499-502 (1991)		
<del>- , _</del>	NPL145	Wiesmüller, K-H., et al., "Novel low-molecular-weight synthetic vaccine against foot-and mouth disease containing a potent B cell and macrophage activator," Vaccine 7:29-33, Butterworth & Co. (1989)		
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·	NPL150	An, L-L., and Whitton, J.L., *A Multivalent Minigene Vaccine, Containing B-Cell, Cytotoxic T-Lymphocyte, and The Epitopes from Several Microbes, Induces Appropriate Responses In Vivo and Confers Protection against More than One Pathogen, *J. Virol. 71:2292-2302, American Society for Microbiology (1997)		
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<u>. :</u>	NPL153	Hanke, T., et al., *Immunogenicities of intravenous and intramuscular administrations of modified vaccinia virus Ankara-based multi-CTL epitope vaccine for human immunodeficiency virus type 1 in mice,* J. Gen. Virol. 79:83-90, Society for General Microbiology (January 1998)		

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	NPL156	Kuhröber, A., et al., "DNA vaccination with plasmids encoding the intracellular (HBcAg) or secreted (HBeAg) form of the core protein of hepatitis B virus primes T cell responses to two overlapping K <sup>b</sup> - and K <sup>d</sup> -restricted epitopes," <i>Int. Immunol.</i> 9:1203-1212, Oxford University Press (1997)	
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	NPL161	Thomson, S.A., et al., *Minimal epitopes expressed in a recombinant polyepitope protein are processed and presented to CD8* cytotoxic T cells: Implications for vaccine design,* <i>Proc Natl. Acad. Sci. USA 92</i> :5845-5849, National Academy of Sciences (1995)	
	NPL162	Thomson, S.A., et al., "Targeting a Polyepitope Protein Incorporating Multiple Class II-Restricted Viral Epitopes to the Secretory/Endocytic Pathway Facilitates Immune Recognition by CD4* Cytotoxic T Lymphocytes: a Novel Approach to Vaccine Design," J. Virol. 72:2246-2252, American Society for Microbiology (March 1998)	
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